

Attorney Docket No.: **P-633 (TI-0020)**  
Inventors: **Taylor and Yu**  
Serial No.: **09/873,645**  
Filing Date: **June 4, 2001**  
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#### **REMARKS**

Claims 13-16 are pending in the instant application and have been rejected. Claim 13 has been amended. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Rejections under 35 U.S.C § 112, first paragraph**

The rejection of claims 13-16 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement has been maintained. It is suggested that the specification fails to disclose what a group of profiles represents/means, how the groups are made or what parameters may be involved in placing one elution profile into one group versus placing an elution profile into a different group. It is further suggested that there is no disclosure as to the significance of the groups. Applicants traverse this rejection.

As is well-known to the skilled artisan and indicated at page 24, line 29, to page 25, line 7, slight run-to-run variations exist in baseline drift, detector signal noise, and retention time, thus making it difficult to match a standardized or control chromatographic profile with a chromatographic profile generated from the separation of components of an unknown sample. Such variations are due to factors including contamination of the separation column and changes in composition of the mobile phase buffer. The instant method solves this problem by using a computer to adjust signal and time data to correct such variations so that chromatographic elution profiles achieve values useful for grouping based on their shape or pattern (see page 16, lines 4-16). The pattern or shape of elution profiles is

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determined by the number, height, width, symmetry, and retention time of peaks (see page 26, lines 19-22). Chromatograms having matching profiles are subsequently grouped together to detect the presence of mutations in the DNA samples being analyzed (see page 27, lines 14-20). As disclosed at page 41, lines 8-29, the disclosed method has utility in analyzing a plurality of samples, including test fragments having previously uncharacterized SNPs or standard fragments having a known sequence, to generate chromatographic profiles which are grouped. A test fragment profile that matches a group with a known SNP is sequenced to confirm the site variation and test fragments which yield a profile that does not match one of the existing groups is characterized as a new mutation.

Thus, Applicants have provided the skilled artisan with the parameters involved in placing one elution profile into one group versus placing an elution profile into a different group, *i.e.*, pattern or shape of the elution profile as determined by the number, height, width, symmetry, and retention time of peaks. Further, the specification clearly teaches that the group of profiles represents matching profiles which have the significance of being used to detect the presence of mutations in the DNA samples being analyzed thereby, *e.g.*, facilitating the discovery of unknown mutations. Thus, in accord with MPEP §2164.01, the instant specification clearly teaches one of skill in the art how to make and how to use the invention as now claimed without undue experimentation. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

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## **II. Rejections under 35 U.S.C § 112, second paragraph**

Claims 13-16 have been rejected under 35 U.S.C. §112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. It is suggested that it is unclear how the intended step of "wherein the processor: (a) overlays said profiles..." in claim 13 limits the recited device. Clarification is requested.

In an earnest effort to facilitate the prosecution of the instant invention, Applicants have amended claim 13 to recite that the processor plots the profiles on a coordinate system for subsequent analysis in steps b-e. Support for this amendment can be found in the schematic of the method provided in Figure 6 and at page 25, lines 14-18. In light of this amendment, withdrawal of this rejection is respectfully requested.

## **III. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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